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10/657,022	09/05/2003	John J.L. Simard	40000220-0032-002	1687

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EXAMINER

SCHWADRON, RONALD B

ART UNIT	PAPER NUMBER
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1644

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02/19/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/657,022

Applicant(s)

SIMARD ET AL.

Examiner

Ron Schwadron, Ph.D.

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-40 is/are pending in the application.
- 4a) Of the above claim(s) 17,27,30-32 and 34-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 18-26,28,29,33 and 40 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- ☐ Notice of Informal Patent Application
- ☐ Other: ____.

1. Applicant's election without traverse of SEQ ID 354 in the reply filed on 8/20/07 is acknowledged.
2. Applicant is required to amend the claims to delete nonelected inventions (aka remove the T cells/TCR from claim 33/40).
3. Applicant is required to update the status of all US applications disclosed in the instant invention. Regarding the amendment of 12/5/07, applicant is not required to indicate that an application has been published as a US patent publication, but is required to indicate whether said application is abandoned or allowed (with the appropriate US Patent number) .
4. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
5. Claims 18-26,28,29,33,40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants arguments have been considered and deemed not persuasive.

The specification does not provide adequate written description of the claimed invention. The legal standard for sufficiency of a patent's (or a specification's) written description is whether that description "reasonably conveys to the artisan that the inventor had possession at that time of the...claimed subject matter", *Vas-Cath, Inc. V. Mahurkar*, 19 USPQ2d 1111 (Fed. Cir. 1991). In the instant case, the specification does not convey to the artisan that the Applicant had possession at the time of invention of the claimed invention.

The instant claims encompass polypeptides having the substitutions of claim 18, part (iii) and polypeptides having "functional similarity" to said peptides. Thus, the claims encompass a vast array of mutant peptides that are not disclosed in the specification and wherein it is unpredictable as to what peptides would have the aforementioned attributes and be functionally active for the various uses of said peptides disclosed in the specification. Karin et al (J. Exp. Med. 180: 2227-2237, 1994) teach that amino acids in an MHC binding peptide that are not the amino acids which participate in MHC binding can have a profound effect on whether or not a peptide is immunogenic. Karin et al teach that a single substitution in an amino acid, wherein said amino acid plays no role in MHC binding can completely abrogate the immunogenicity of an otherwise immunogenic peptide (especially Summary and Table 1). Thus Karin et al establish that it is unpredictable as to what amino acid residues not involved in MHC binding of a peptide can be changed wherein the peptides remain immunogenic.

In view of the aforementioned problems regarding description of the claimed invention, the specification does not provide an adequate written description of the invention claimed herein. See *The Regents of the University of California v. Eli Lilly and Company*, 43 USPQ2d 1398, 1404-7 (Fed. Cir. 1997). In *University of California v. Eli Lilly and Co.*, 39 U.S.P.Q.2d 1225 (Fed. Cir. 1995) the inventors claimed a genus of DNA species encoding insulin in different vertebrates or mammals, but had only described a single species of cDNA which encoded rat insulin. The court held that only the nucleic acids species described in the specification (i.e. nucleic acids encoding rat insulin) met the description requirement and that the inventors were not entitled to a claim encompassing a genus of nucleic acids encoding insulin from other vertebrates, mammals or humans, *id.* at 1240. In the instant case, the facts are similar to those disclosed in *University of California v. Eli Lilly and Co.* The Federal Circuit has held that if an inventor is "unable to envision the detailed constitution of a gene so as to distinguish it from other materials. . . conception has not been achieved until reduction to practice has occurred", *Amgen, Inc. v. Chugai Pharmaceutical Co, Ltd.*, 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991). Attention is also directed to the decision of *The Regents of the University of California v. Eli Lilly and Company* (CAFC, July 1997) wherein is stated: The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re*

Wilder, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. Thus, as we have previously held, a cDNA is not defined or described by the mere name "cDNA," even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA. See Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606.

Regarding applicants comments, The instant claims encompass polypeptides having the substitutions of claim 18, part (iii) and polypeptides having "functional similarity" to said peptides. Thus, the claims encompass a vast array of mutant peptides that are not disclosed in the specification and wherein it is unpredictable as to what peptides would have the aforementioned attributes and be functionally active for the various uses of said peptides disclosed in the specification. Karin et al (J. Exp. Med. 180: 2227-2237, 1994) teach that amino acids in an MHC binding peptide that are not the amino acids which participate in MHC binding can have a profound effect on whether or not a peptide is immunogenic. Karin et al teach that a single substitution in an amino acid, wherein said amino acid plays no role in MHC binding can completely abrogate the immunogenicity of an otherwise immunogenic peptide (especially Summary and Table 1). Thus Karin et al establish that it is unpredictable as to what amino acid residues not involved in MHC binding of a peptide can be changed wherein the peptides remain immunogenic. In view of the aforementioned problems regarding description of the claimed invention, the specification does not provide an adequate written description of the invention claimed herein. See *The Regents of the University of California v. Eli Lilly and Company*, 43 USPQ2d 1398, 1404-7 (Fed. Cir. 1997). In *University of California v. Eli Lilly and Co.*, 39 U.S.P.Q.2d 1225 (Fed. Cir. 1995) the inventors claimed a genus of DNA species encoding insulin in different vertebrates or mammals, but had only described a single species of cDNA which encoded rat insulin. The court held that only the nucleic acids species described in the specification (i.e. nucleic acids encoding rat insulin) met the description requirement and that the

inventors were not entitled to a claim encompassing a genus of nucleic acids encoding insulin from other vertebrates, mammals or humans, *id.* at 1240. In the instant case, the facts are similar to those disclosed in *University of California v. Eli Lilly and Co.* The Federal Circuit has held that if an inventor is "unable to envision the detailed constitution of a gene so as to distinguish it from other materials. . .conception has not been achieved until reduction to practice has occurred", *Amgen, Inc. v. Chugai Pharmaceutical Co, Ltd.*, 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991). Attention is also directed to the decision of *The Regents of the University of California v. Eli Lilly and Company* (CAFC, July 1997) wherein is stated: **The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention.** See *In re Wilder*, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). **Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.** Thus, as we have previously held, a cDNA is not defined or described by the mere name "cDNA," even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA. See *Fiers*, 984 F.2d at 1171, 25 USPQ2d at 1606.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 1644

7. The rejection of claims 1-16,18-26,28,29 under 35 U.S.C. 102(b) as being anticipated by Fikes et al. (WO 01/45728) for the reasons elaborated in the previous Office Action is withdrawn in view of the amended claims and cancellation of claims that have been cancelled.

8. Claims 33,40 are rejected under 35 U.S.C. 102(b) as being anticipated by Fikes et al. (WO 01/45728).

Fikes et al. teach the peptide of SEQ. ID. 67 (see pages 237, 240 and Table 24). The peptide is 10 amino acids long. The various functional activities of the peptide recited in the claims are inherent properties of said peptide. Fikes et al. teach a composition of said peptide and an excipient (see claim 24) and a method of making said vaccine (see page 31).

Regarding applicants comments, the claims under consideration read on a single ingredient recited in the claim and do not require two epitopes (aka they read on compositions/methods that only use the peptide of SEQ ID NO:67).

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 18-26,28,29,33,40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fikes et al. (WO 01/45728) in view of Thomson et al. (WO 01/090197 A1).

Fikes et al. teach the peptide of SEQ. ID. 67 (see pages 237, 240 and Table 24). The peptide is 10 amino acids long. The various functional activities of the peptide recited in the claims are found in said peptide. Applicant has indicated that the elected species reads on all of the claims currently under consideration (see page 6, fourth paragraph of the response filed 12/11/06). The recitation of a method of determining the binding affinity carries no patentable weight in the instant product claims. The peptide can have added amino acids (see claim 2 of Fike et al.) at the N-terminus (see page 16, line 5). Fikes et al. teach analogs of said peptides (see page, last paragraph). Fikes et al. teach a composition of said peptide and an excipient (see claim 24) and a method of making said vaccine (see page 31). Fikes et al. teach a composition of said peptide with a pAPC (dendritic cell) and/or GM-CSF (see pages 32-33). Fikes et al. teach a cell that expresses the claimed peptide and contains a CpG polynucleotide and/or nucleic acid encoding an adjuvant such as GM-CSF (see page 35, last two paragraphs, and page 36, penultimate paragraph). The composition can contain a second epitope (see page 32 and claim 25). Fikes et al. do not teach that the composition contains the peptide of SEQ ID NO:354. The language "epitope having" (aka comprising) "the sequence selected from the group consisting of" is interpreted as open in scope (aka equivalent in scope to comprising) wherein the claim encompasses SEQ ID NO:354 found in a larger peptide. Thomson et al. disclose an epitope comprising the peptide of SEQ. ID NO:354 (see Example 3 and Figure 27 (MART)). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Fikes et al. disclose the claimed composition except for the second epitope comprising the peptide of SEQ. ID NO:354 whilst Thomson et al. disclose said epitope and Fikes et al. disclose that the composition can contain additional epitopes. One of ordinary skill in the art would have been motivated to do the aforementioned because Fikes et al. disclose that the composition can contain additional epitopes.

11. No claim is allowed.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached on Monday-Thursday 7:30-6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on 571 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Application/Control Number: 10/657,022


Page 9

Art Unit: 1644

Ron Schwadron, Ph.D.

Primary Examiner

Art Unit 1644


RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP ~~1644~~ 1644